UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,638	08/16/2001	Franz-Georg Hanisch	050001	2700

23464 7590 05/08/2009

BUCHANAN INGERSOLL & ROONEY PC
P.O. BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
05/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	09/931,638	HANISCH ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date. _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

1. The declaration filed January 5, 2007 is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The declaration is defective because: The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 602.

The declaration identifies application Serial No. 09/940,253 filed August 17, 2001, rather than Serial No. 09/931,638 filed August 16, 2001. The examiner recognizes that there were significant processing problems involving this application after it was filed, as set forth in the petition filed January 5, 2007. However, in the absence of some official determination by appropriate Office personnel that this application and application Serial No. 09/940,253 are the same application, a new declaration identifying this application is required.

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on February 17, 1999. While the copy of the postcard receipt included with the petition filed January 5, 2007 shows that a certified copy of the 199 06 615.9 application was filed January 22, 2007 as required by 35 U.S.C. 119(b), the copy has not been scanned into the Image File Wrapper for this application (or for application serial no. 09/940,253). The certified copy submitted by Applicants is lost, and needs to be-resubmitted in order to perfect Applicants' claim for priority.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

The amino acid sequence appearing at page 1, fourth paragraph, line 5, of the specification is subject to the sequence disclosure rules, but is not included in the Sequence Listing filed January 5, 2007.

Applicant must provide a substitute computer readable form (CRF) copy of the Sequence Listing, a substitute paper copy of the Sequence Listing as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 1.825(a) and (b).

The computer readable form copy of the Sequence Listing filed January 5, 2007 was approved by STIC for matters of format.

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/DE00/00440, filed February 17, 2000. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications.

5. The disclosure is objected to because of the following informalities: A SEQ ID NO must be inserted after the amino acid sequence occurring at page 1, fourth paragraph, line 5, of the specification. See 37 CFR 1.821(d). Appropriate correction is required.

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-5 and 7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1-5 and 7 appear to recite products which are produced by naturally-occurring human carcinoma cells. See page 2, second and third paragraphs, of the specification. Note the lack of any limitation such as "isolated" or "purified". Accordingly, the claims embrace products of nature, which do not constitute patentable subject matter.

8. Claim 7 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A "Use' is not a statutory class of invention.

9. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite because it is not clear if the positions which deviate from the VNTR domain are limited to positions 9, 18, and 19, or if other positions in the peptide variants can also deviate from the VNTR domain as long as at least one of positions 9, 18, and 19 also deviates. Claim 1, line 2, uses the conjunction "and" between "9" and "18", but uses a different conjunction "and/or" between "18" and "19". It is not clear if the different conjunctions mean that, e.g., both positions 9 and 18 must deviate simultaneously, or that deviation at position 19 is an alternative to deviation at positions 9 and 18, or that deviation at position 9 is required and in addition deviation at one of positions 18 and 19 is also required. The interpretation of "well-known" at claim 1, line 3, is unclear. It is not clear if this term should be interpreted as referring to, e.g., the sequence of the VNTR domain occurring in a majority of non-cancerous cells, or any

known sequence of the VNTR domain occurring in any cell. It is not clear if "well-known" includes, e.g., any known VNTR domain sequence, or any published VNTR domain sequence. It is not clear at what point in time "well-known" is to be determined, e.g., at the time the invention was made, at the time of patenting, or at the time of a potential act of infringement. The interpretation of the forward slash / between "substances" and "reagents" at claim 4, line 1, and at claim 5, line 1, is unclear. It is not clear if "reagents" is an alternative intended use for "immunogenic substances" and "antigenic substances", or if "reagents" is being used as a synonym. There is no antecedent basis in the claims for the phrase "the primer sequences" at claim 6, line 2. It is not clear what constitutes a "use" as is recited in instant claim 7, e.g., it is not clear if Applicants are claiming a product with an intended use limitation, or a method of using a product. To the extent that the latter is intended, the claims are indefinite because they are drawn to a method, but do not recite any positive process steps. Claim 7 is indefinite because the "especially…" phrase at lines 3-4 makes it unclear as to whether or not the scope of the claim is to be limited to the specific embodiment, i.e. to the generation of effective vaccines in a tumor therapeutic context. It is suggested that the phrase could be deleted and made the subject matter of a further dependent claim.

10. Claims 1-7 are objected to because of the following informalities: At claim 1 line 2, the first occurrence of the abbreviation "aa", i.e. "amino acids", should be spelled out. At claim 7, line 3, the word "effective" should be deleted as being at best redundant. At claim 7, line 4, the word "context" should be deleted as being at best redundant. Appropriate correction is required.

11. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The subject matter of claim 6 is not recited anywhere in the specification.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1, 4, 5, and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1, 4, 5, and 7 recite peptide variants of MUC1 within the VNTR domain differing from the well-known VNTR domain sequence at least at positions 9, 18, or 19. (Exact interpretation of the scope of the claims is not possible in view of significant issues under 35 U.S.C. 112, second paragraph. See section 9 above.) The specification and claims do not set forth any limitations as to what deviations may occur at these positions, e.g., the type of amino acid being substituted at these positions, or even the deletion or insertion of amino acids at these positions. Further, the claims may also embrace additional amino acid substitutions, deletions, or insertions at positions other than 9, 18, or 19. The claimed genus is highly variable because a significant number of structural differences between genus members is permitted. However, the specification discloses only three peptide variants of MUC1 within the VNTR domain, and it is not predictable as to whether other peptide variants exist, and if they exist, what their sequences might be. The structure and function of three peptide variants does not provide any guidance as

to whether other peptide variants exist, and if so, what the structure and function of these peptide variants is. One of skill in the art would conclude that Applicants were not in possession of the claimed genus because the description of only three members of this genus is not representative of the peptide variants of this genus and is insufficient to support the claims.

14. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 6 recites a kit comprising primer sequences corresponding to peptide variants of MUC1 within the VNTR domain differing from the well-known VNTR domain sequence at least at positions 9, 18, or 19. The kits are to be used to determine the identity and incidence of DNA mutations within the VNTR domain. As noted in section 13 above, the genus of peptide variants is highly variable. Further, the primer sequences are only functionally defined. Applicants do not disclose any primer sequences which correspond to the peptide variants, and do not disclose any partial structure or structure-function correlation for such primer sequences. The specification does not contain any disclosure with respect to primer sequences, including structure of the primer sequence necessary to uniquely identify the DNA which encodes the peptide variants (unique identification being necessary in order to achieve the claimed function of determining the identity and incidence of DNA mutations). One of skill in the art would conclude that Applicants were not in possession of the claimed genus because the description of no members of this genus is not representative of the peptide variants of this genus and is insufficient to support the claims.

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1 and 3-7 are rejected under 35 U.S.C. 102(b) as being anticipated by the Japanese Patent Application 7-51065. The Japanese Patent Application '065 teaches a peptide, and DNA encoding the peptide, wherein the peptide comprises both Applicants' SEQ ID NOS:3 and 1. See the sequence bridging pages 7 and 8, and especially amino acid residues 18-37 and amino acid residues 38-57. With respect to instant claims 4-7, note that intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art.

17. Finn et al (U.S. Patent No. 5,827,666) is cited as art of interest, to show the general state of the art.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
May 6, 2009